PATENT
ATTORNEY DOCKET NO.: SSK-51(19354)

UNITED STATES PATENT APPLICATION

ENTITLED

ELASTOMERIC GLOVE COATING

BY

ROBERT A. JANSSEN

DAVID W. JOHNSON

AND

PAM MAYBERRY

ELASTOMERIC GLOVE COATING

Background of the Invention

Elastomeric gloves are formed to fit tightly against a user's hand and provide good gripping and tactile characteristics during use. In addition, elastomeric gloves are normally liquid-impermeable to provide a barrier between the wearer and the environment in which the gloves are used. Unfortunately, these desired characteristics of elastomeric gloves create a harsh environment for the wearer's skin. For example, perspiration is a common problem for glove wearers, and the resulting moist environment may lead to various skin problems, including, for example, growth of fungi and yeast, as well as bacterial and viral infections of the skin. In addition, those who utilize elastomeric gloves in the medical field frequently clean their hands with soap or sanitary alcohol formulations. This constant cleaning is harsh on the skin, causing excessive skin dryness that may exacerbate other skin problems.

In the past, the wearer-contacting surface of elastomeric gloves was treated with a powder, such as talc or calcium carbonate powder, to absorb moisture and alleviate some of the problems faced by wearers of the glove. The powder also facilitated donning. However, while powders may still be acceptable in certain applications, they are typically undesired in surgical or cleanroom-type environments. As such, a need currently exists for an improved glove that is capable of relieving some of the problems that might stem from the harsh environment to which the wearer's hand is exposed during use.

Summary of the Invention

In accordance with one embodiment of the present invention, an elastomeric glove is disclosed that comprises a substrate body including a layer made of an elastomeric material. The substrate body defines an inner surface and an outer surface. A coating overlies the inner surface of the substrate body and defines a user-contacting surface of the glove. The coating comprises a crosslinked hydrogel network within which is retained an active agent capable of imparting a benefit to a user. The active agent is releasable from the network when the coating is contacted with an aqueous environment.

In accordance with another embodiment of the present invention, an elastomeric article is disclosed that comprises a substrate body including a layer

made of an elastomeric material. The elastomeric material is selected from the group consisting of styrene-ethylene-butylene-styrene block copolymers, styrene-isoprene-styrene block copolymers, styrene-butadiene-styrene block copolymers, styrene-isoprene block copolymers, styrene-butadiene block copolymers, natural rubber latex, nitrile rubbers, isoprene rubbers, chloroprene rubbers, polyvinyl chlorides, silicone rubbers, and combinations thereof. The substrate body defines a surface over which lies a coating. The coating comprises a substantially water-insoluble, crosslinked hydrogel network within which is retained an active agent capable of imparting a benefit. The active agent is releasable from the network when the coating is contacted with water.

In accordance with still another embodiment of the present invention, a method for forming an elastomeric glove containing a substrate body and a coating overlying a surface of the substrate body is disclosed. The method comprises dipping a hand-shaped former into at least one bath containing an elastomeric polymer to form the substrate body of the glove. An aqueous solution is applied to the substrate body or the hand-shaped former to form the coating of the glove. The aqueous solution contains at least one hydrogel-forming polymer and an active agent. The hydrogel-forming polymer is crosslinked to form a hydrogel network, wherein the active agent is retained within the hydrogel network and is releasable therefrom when the coating is contacted with an aqueous environment.

In accordance with yet another embodiment of the present invention, a method for forming an elastomeric glove containing a substrate body and a coating overlying a surface of the substrate body is disclosed. The method comprises dipping a hand-shaped former into at least one bath containing an elastomeric polymer to form the substrate body of the glove. An aqueous solution is applied to the substrate body or the hand-shaped former to form the coating of the glove. The aqueous solution contains at least one hydrogel-forming polymer. The hydrogel-forming polymer is crosslinked to form a hydrogel network. An active agent is incorporated into the hydrogel network, the active agent being releasable therefrom when the coating is contacted with an aqueous environment.

Other features and aspects of the present invention are discussed in greater detail below.

Brief Description of the Drawings

A full and enabling disclosure of the present invention, including the best mode thereof, directed to one of ordinary skill in the art, is set forth more particularly in the remainder of the specification, which makes reference to the appended figures in which:

Fig. 1 is a perspective view of one embodiment of an elastomeric glove made according to the invention;

Fig. 2 is a cross-sectional view of the glove illustrated in Fig. 1 taken along a line 2-2; and

Fig. 3 is a graphic illustration of the results obtained in the Example, in which the absorbance of the dye is shown for various diffusion times.

Repeat use of reference characters in the present specification and drawings is intended to represent same or analogous features or elements of the invention.

Detailed Description of Representative Embodiments

Reference now will be made in detail to various embodiments of the invention, one or more examples of which are set forth below. Each example is provided by way of explanation of the invention, not limitation of the invention. In fact, it will be apparent to those skilled in the art that various modifications and variations may be made in the present invention without departing from the scope or spirit of the invention. For instance, features illustrated or described as part of one embodiment, may be used on another embodiment to yield a still further embodiment. Thus, it is intended that the present invention covers such modifications and variations as come within the scope of the appended claims and their equivalents.

In general, the present invention is directed to an elastomeric article, such as a condom or glove, which contains a hydrogel coating. The present inventors have discovered that the hydrogel coating is capable of improving donning (damp and/or dry) and also imparting certain other benefits to a user of the article. Specifically, the hydrogel coating includes an active agent that is retained within a crosslinked hydrogel network. When the hydrogel coating is exposed to an aqueous environment, it swells, allowing the active agent to diffuse through pores and contact the skin of a user.

Referring to Figs. 1-2, for example, one embodiment of an elastomeric glove 20 is illustrated that may be placed over the hand of a user 22. The glove 20 includes a substrate body 24 having the basic shape of the glove. The substrate body 24 may generally be formed from any of a variety of natural and/or synthetic elastomeric materials known in the art. For instance, some examples of suitable elastomeric materials include, but are not limited to, S-EB-S (styrene-ethylene-butylene-styrene) block copolymers, S-I-S (styrene-isoprene-styrene) block copolymers, S-B-S (styrene-butadiene-styrene) block copolymers, S-I (styrene-isoprene) block copolymers, S-B (styrene-butadiene) block copolymers, natural rubber latex, nitrile rubbers, isoprene rubbers, chloroprene rubbers, polyvinyl chlorides, silicone rubbers, and combinations thereof. Other suitable elastomeric materials that may be used to form the substrate body 24 may be described in U.S. Patent Nos. 5,112,900 to Buddenhagen, et al.; 5,407,715 to Buddenhagen, et al.; 5,900,452 to Plamthottam; 6,288,159 to Plamthottam; and 6,306,514 to Weikel, et al., which are incorporated herein in their entirety by reference thereto for all purposes.

In one embodiment, the substrate body 24 is formed from natural rubber latex. To form the substrate body 24 from natural latex, a former is initially dipped into a coagulant bath that facilitates later stripping of the glove from the former. The coagulant bath may include calcium carbonate and/or calcium nitrate. Thereafter, the coagulant-coated former is dried and subsequently dipped into one or more latex baths. The resulting latex layer(s) are then typically leached in water to extract a large percentage of the water-soluble impurities in the latex and coagulant. The coated former is then dried to cure (i.e., crosslink) the rubber. It should be understood that the conditions, process, and materials used in forming natural rubber gloves are well known in the art, and are not critical to the practice of the present invention.

Regardless of the particular material used to form the substrate body 24, the glove 20 also includes a coating 26 that is present on an inner surface 28 defined by the substrate body 24. In this embodiment, the coating 26 defines a wearer-contacting surface 27 of the glove 20 that contacts the body of the user 22. The coating 26 serves dual purposes in the present invention. Specifically, the coating 26 has a low coefficient of friction that facilitates donning of the glove 20

when the user's hand is either dry or wet, i.e., dry and damp donning. The low coefficient of friction may be imparted through surface texture and/or through the lubricity of the materials used to form the coating 26. In addition to facilitating donning, another purpose of the coating 26 is to controllably release an active agent contained therein for contacting a user's skin and providing some desired benefit. The present inventors have discovered that such dual purposes may be accomplished by forming the coating 26 from a hydrogel within which is retained the active agent.

Generally speaking, any of a variety of polymers may be utilized in the present invention to form the hydrogel. Typically, the polymer is utilized that is formed from at least one hydrogel-forming monomer that is hydrophilic and water-soluble. There are many known hydrophilic, water-soluble monomers that may be used in the present invention to form the hydrogel polymer. Some examples of such monomers include, but are not limited to, vinyl pyrrolidone, hydroxyethyl acrylate or methacrylate (e.g., 2-hydroxyethyl methacrylate), hydroxypropyl acrylate or methacrylate, acrylic or methacrylic acid, acrylic or methacrylic esters or vinyl pyridine, acrylamide, vinyl alcohol, ethylene oxide, derivatives thereof, and so forth. Other examples of suitable monomers are described in U.S. Patent Nos. 4,499,154 to James, et al., which is incorporated herein in its entirety by reference thereto for all purposes. The resulting polymers may be homopolymers or interpolymers (e.g., copolymer, terpolymer, etc.), and may be nonionic, anionic, cationic, or amphoteric. In addition, the polymer may be of one type (i.e., homogeneous), or mixtures of different polymers may be used (i.e., heterogeneous).

To form the hydrogel, the polymer(s) are crosslinked using any known crosslinking technique, including known ionic or covalent crosslinking techniques. For example, in some embodiments, a crosslinking agent may be utilized to facilitate crosslinking. Examples of crosslinking agents include, but are not limited to, polyhydric alcohols (e.g., glycerol); polyaziridine compounds (e.g., 2,2-bishydroxymethyl butanoltris[3-(1-aziridine) propionate] or triaziridine); epoxy compounds; haloepoxy compounds (e.g., epicholorhydrin); aldehyde compounds (e.g., urea-formaldehyde, melamine-formaldehyde, hydantoin-formaldehyde, glutaraldehyde, glyoxal, malonaldehyde, succinaldehyde, adipaldehyde, or

dialdehyde starch); polyisocyanate compounds (e.g., 2,4-toluene diisocyanate); etc. Crosslinking may be carried out before, during, and/or after application of the polymer to the surface 28 of the substrate body 24. For example, in one embodiment, an aqueous solution containing a crosslinking agent and polymer is applied to the surface 28. Thereafter, the mixture is cured at elevated temperatures. Besides thermal activation, crosslinking may also be carried out using other well-known techniques. For example, crosslinking may be induced with ionizing radiation, which is radiation having an energy sufficient to either directly or indirectly produce ions in a medium. Some suitable examples of ionizing radiation that may be used in the present invention include, but are not limited to, electron beam radiation, natural and artificial radio isotopes (e.g., α, β, and γ rays), x-rays, neutron beams, positively charged beams, laser beams, and so forth. Electron beam radiation, for instance, involves the production of accelerated electrons by an electron beam device. Electron beam devices are generally well known in the art. For instance, in one embodiment, an electron beam device may be used that is available from Energy Sciences, Inc., of Woburn, Massachusetts under the name "Microbeam LV." Other examples of suitable electron beam devices are described in U.S. Patent Nos. 5,003,178 to Livesay; 5,962,995 to Avnery; 6,407,492 to Avnery, et al., which are incorporated herein in their entirety by reference thereto for all purposes.

Regardless of the technique utilized, crosslinking forms a hydrogel constituted by a three-dimensional network that is substantially water-insoluble. Thus, when exposed to water, the hydrogel does not dissolve, but instead may absorb a certain amount of water. For example, the hydrogel is capable of achieving a water content of from about 20% to about 90%, in some embodiments from about 35% to about 85%, and in some embodiments, from about 50% to about 80%. The water content of the hydrogel is determined as follows:

$$\% \text{ water} = 100 \times \frac{(\text{weight of wet hydrogel} - \text{weight of dry hydrogel})}{(\text{weight of wet hydrogel})}$$

Upon absorbing water, the hydrogel swells, thereby increasing the area between crosslinks to form pores. For example, at its highest water content, the hydrogel may possess pores having an average size of from about 1 nanometer to about 10

microns, in some embodiments from about 10 nanometers to about 1 micron, and in some embodiments, from about 50 nanometers to about 100 nanometers.

When present on the glove 20, the expected conditions of use expose the hydrogel to moisture from a variety of sources, such as water present on a user's hand from washing, moisture secreted by mammalian sweat glands, and so forth. For instance, human sweat glands are of two types, eccrine and apocrine. The apocrine glands occur only in the armpits and about the ears, nipples, navel, and anogenital region, are scent glands. Eccrine glands, however, are present throughout the body, including the hands, and are designed to regulate the temperature of the body. Obviously, the amount of fluid secreted by the eccrine glands depends on body temperature; however, even on cold days, some transepidermal water loss will likely occur. Because elastomeric gloves (e.g., surgical gloves) often fit tightly over a user's hand and do not allow outside air to readily cool the skin, the temperature of the user's hand is likely to increase when wearing the glove. This temperature increase may also cause additional fluid to be secreted by the eccrine glands.

Thus, when placed adjacent to a user's skin, the hydrogel will invariably be exposed to fluids secreted by eccrine glands or from some other source. This exposure leads to an increase degree of hydration for the hydrogel and a corresponding increase in the size of the hydrogel pores. As the pore size increases, the active agent within the crosslinked hydrogel network may be released. Once released, the active agent may interact directly with epithelial tissue at the cellular level to provide a benefit to the skin. Alternatively, the active agent may interact with components at or near the skin surface to provide the desired benefit.

The active agent may be incorporated into the hydrogel before, during, and/or after its formation. In one embodiment, for example, the active agent may be mixed with the hydrogel-forming polymer and crosslinking agent prior to crosslinking. When crosslinked, the active agent is retained within the three-dimensional network. As stated, the active agent may also be applied after formation of the hydrogel. For example, the hydrogel may be applied with an aqueous solution containing the active agent. As described above, the aqueous solution hydrates the hydrogel and causes an increase in porosity. Due to this

increased porosity, the active agent may diffuse through the pores and into the crosslinked hydrogel network. The hydrogel is subsequently dried to retain the active agent therein. Typically, the size of the active agent is smaller than the pore size of the hydrogel when dry so that it remains physically retained within the hydrogel network. Apart from being physically retained within the hydrogel, the active agent may also be chemically bonded to the hydrogel, such as through covalent, ionic, or hydrogen bonding.

Generally speaking, the "active agent" may be any compound or mixture thereof that may produce a desired result. Whether in solid or liquid form, the active agent typically possesses a sufficient solubility or miscibility in an aqueous system to render it capable of being released through the pores of the hydrogel network. Examples of such active agents include, but are not limited to, drugs, skin-conditioners, botanical agents, etc. "Drugs" include any physiologically or pharmacologically active substance that produces a localized or a systemic effect in animals. The drugs that may be delivered include, but are not limited to, anti-inflammatory agents, immunosuppressives, antimicrobials, anesthetics, analgesics, hormones, antihistamines, and so forth. Numerous such compounds are known to those of skill in the art and described, for example, in The Pharmacological Basis of Therapeutics, Hardman, Limbird, Goodman & Gilman, McGraw-Hill, New York, (1996), as well as U.S. Patent Nos. 6,419,913 to Niemiec, et al.; 6,562,363 to Mantelle, et al.; 6,593,292 to Rothbard, et al.; 6,567,693 to Allen, Jr.; and 6,645,181 to Lavi, et al., all of which are incorporated herein in their entirety by reference thereto for all purposes. Although several examples of active agents are described herein, it should be understood that the present invention is by no means limited to any particular active agent. In fact, any active agent having any benefit whatsoever to a user may be utilized in accordance with the present invention.

In this regard, one class of suitable drugs includes anti-inflammatory agents, such as glucocorticoids (adrenocorticoid steroids). Exemplary glucocorticoids include, for example, hydrocortisone, prenisone (deltasone) and predrisonlone (hydeltasol). Glucocorticoids may be used to treat inflammatory skin diseases, such as eczema (e.g., atopic dermatitis, contact dermatitis, and allergic dermatitis), bullous disease, collagen vascular diseases, sarcoidosis, Sweet's disease,

pyoderma gangrenosum, Type I reactive leprosy, capillary hemangiomas, lichen planus, exfoliative dermatitis, erythema nodosum, hormonal abnormalities (including acne and hirsutism), toxic epidermal necrolysis, erythema multiforme, cutaneous T-cell lymphoma, discoid lupus erythematosus, and so forth. Retinoids, such as retinol, tretinoin, isotretinoin, etretinate, acitretin, and arotinoid, may also be used. Conditions that are possibly treatable using retinoids include, but are not limited to, acne, keratinization disorders, psoriasis, cutaneous aging, discoid lupus erythematosus, scleromyxedema, verrucous epidermal nevus, subcorneal pustular dermatosis, Reiter's syndrome, warts, lichen planus, acanthosis nigricans, sarcoidosis, Grover's disease, porokeratosis, and so forth. Other suitable anti-inflammatory drugs are COX-2 inhibitors, such as celecoxib, meloxicam, rofecoxib, and flosulide. These drugs inhibit the production of the COX-2 (cyclooxygenase-2) enzyme induced by pro-inflammatory stimuli in migratory cells and inflamed tissue. In addition, nonsteroidal anti-inflammatory drugs (NSAIDs) may also be utilized. Examples of NSAIDs include, but are not limited to, Aspirin, Ibuprofen, Indomethacin, Phenylbutazone, Bromfenac, Sulindac, Nabumetone, Ketorolac, Mefenamic Acid, and Naproxen.

Immunosuppressive drugs constitute an additional class of drugs from which the active agent may be selected. These drugs may be used to treat hyperproliferative diseases, such as psoriasis, as well as immune diseases, such as bullous dermatoses and leukocytoclastic vasculitis. Examples of such drugs include, but are not limited to, antimetabolites, such as methotrexate, azathioprine, fluorouracil, hydroxyurea, 6-thioquanine, mycophenolate, chlorambucil, vinicristine, vinblasrine and dactinomycin; alkylating agents, such as cyclophosphamide, mechloroethamine hydrochloride, carmustine, taxol, tacrolimus and vinblastine; and so forth.

Another class of suitable drugs includes antimicrobial agents, e.g., antibacterial, antifungal, antiviral, etc. Antibacterial agents are useful for treating conditions such as acne, cutaneous infections, and so forth. For instance, some suitable antimicrobial agents include, but are not limited to, bisphenols, such as 2,4,4'-trichloro-2'-hydroxydiphenyl ether (triclosan); quaternary ammonium compounds, such as benzalkonium chloride; esters of parahydroxy benzoic acid, such as methyl parabens; formaldehyde and formaldehyde donors, such as 2-

bromo-2-nitro-1,3 propanediol, hydantoins, diazolidinyl urea, and imidazolidinyl urea; alkylisothizaolinones; phenoxyethanol; chlorhexidine gluconate; parachlorometaxylenol (PCMX); chitosan, such as chitosan pyrrolidone carboxylate; combinations thereof, and so forth. Antifungal agents may also be used to treat conditions, such as tinea corporis, tinea pedis, onychomycosis, candidiasis, tinea versicolor, onychomycosis, and so forth. Examples of antifungal agents include, but are not limited to, azole antifungals such as itraconazole, myconazole and fluconazole. Examples of antiviral agents include, but are not limited to, acyclovir, famciclovir, and valacyclovir. Such agents are useful for treating viral diseases, such as herpes.

Antihistamines are still another class of suitable drugs. Examples of such antihistamines include, for example, terfenadine, astemizole, lorotadine, cetirizine, acrivastine, temelastine, cimetidine, ranitidine, famotidine, nizatidine, and so forth. These agents may be used to treat conditions such as pruritus, atopic dermatitis, contact dermatitis, psoriasis, etc. Further, local anesthetics constitute another class of drugs that may be used. Examples of such local anesthetics include, but are not limited to, lidocaine, bupibacaine, novocaine, procaine, tetracaine, benzocaine, mepivacaine, etidocaine, 2-chloroprocaine hydrochloride, and so forth.

Other than drugs, various other active agents may be released from the glove according to the present invention. For instance, in some embodiments, the active agent may be a skin-conditioner that improves moisture retention, softness, texture, and other properties of the skin. One example of such a skin-conditioner is an emollient that helps restore dry skin to a more normal moisture balance. Specifically, emollients act on the skin by supplying fats and oils that blend with skin, making it pliable, repairing some of the cracks and fissures in the stratum corneum, and forming a protective film that traps water in the skin. Emollients that may be suitable for use in the present invention include, but are not limited to, beeswax, butyl stearate, cermides, cetyl palmitate, eucerit, isohexadecane, isopropyl palmitate, isopropyl myristate, mink oil, mineral oil, nut oil, oleyl alcohol, petroleum jelly or petrolatum, glyceral stearate, avocado oil, jojoba oil, lanolin (or woolwax), lanolin derivatives such as lanolin alcohol, retinyl palmitate (a vitamin A derivative), cetearyl alcohol, squalane, squalene, stearic acid, stearyl alcohol,

myristal myristate, various lipids, decyl oleate and castor oil. Another possible skin conditioner is a humectant, which may supply the skin with water by attracting moisture from the air and holding it on the skin. Humectants that may be suitable in the present invention include, but are not limited to, alanine, glycerin, polyethylene glycol, propylene glycol, butylene glycol, hyaluronic acid, Natural Moisturizing Factor (a mixture of amino acids and salts that are among the skin's natural humectants), saccharide isomerate, sodium lactate, sorbitol, urea, and so forth. Still other suitable skin-conditioners include antioxidants, a group of substances that prevent or slow the oxidation process of skin, thereby protecting it from premature aging. Exemplary antioxidants include, but are not limited to, Vitamin E, Vitamin E derivatives, Vitamin C, Vitamin C derivatives, Vitamin A palmitate, butylated hydroxy toluene, phenols, phenolic derivatives, thiodipropionate esters, hydroquinone derivatives, alkylated aryl amine, combinations thereof, and so forth.

The active agent may also be a botanical agent that may potentially reduce swelling, itching, reddening, etc. Examples of some botanicals that may be used include, but are not limited to, Agnus castus, aloe vera, comfrey, calendula, dong quai, black cohosh, chamomile, evening primrose, Hypericum perforatum, licorice root, black currant seed oil, St. John's wort, tea extracts, lemon balm, capsicum, rosemary, Areca catechu, mung bean, borage seed oil, witch hazel, fenugreek, lavender, soy, almonds, chamomile extracts (e.g., bisabolol), elder flowers, honey, safflower oil, and elastin.

The coating 26 may be formed using any suitable method. For example, techniques, such as dipping, spraying, patting, tumbling, etc., may be utilized in the present invention. Although it is normally desired that the coating 26 cover the entire surface 28, it may also cover only a portion of the surface 28. The average thickness of the coating 26, when dry, may range from about 0.05 to about 50 micrometers, in some embodiments from about 0.1 to about 20 micrometers, and in some embodiments, from about 1 to about 10 micrometers. In addition, the dried coating may comprise from about 0.0001 to about 1 gram per gram of the glove, in some embodiments from about 0.001 to about 0.5 grams per gram of the glove, and in some embodiments, from about 0.01 to about 0.2 grams per gram of the glove 20. Further, besides covering the surface 28, an additional coating may

also cover an outer surface 30 (e.g., gripping surface) of the substrate body 24 that is the same or different than the coating 26. For instance, when present on the surface 30, the hydrogel coating 26 may controllably release an active agent that imparts certain benefits to a person with whom the glove 20 contacts.

An elastomeric article made in accordance with the present invention may generally be formed using a variety of processes known in the art. In fact, any process capable of making an elastomeric article may be utilized in the present invention. For example, elastomeric article formation techniques may employ dipping, spraying, halogenation, drying, curing, as well as any other technique known in the art. In this regard, one embodiment of a method of dip-forming a natural rubber latex glove will now be described in more detail. Although a batch process is described herein, it should be understood that semi-batch and continuous processes may also be utilized in the present invention.

Initially, any well-known former, such as formers made from metals, ceramics, or plastics, is provided. The former is dried to remove water residue by conveying it through a preheated oven. The preheated former is then dipped into a bath containing a coagulant, a surfactant, water, and optionally other ingredients, such as a powder. The coagulant may contain calcium ions (e.g., calcium nitrate) to break the protection system of the emulsion, thereby allowing the latex to deposit on the former. The powder may be calcium carbonate powder, which later acts as a release agent. The surfactant provides good wetting to avoid forming a meniscus and trapping air between the form and deposited latex, particularly in the cuff area. As noted above, the former has been preheated in the drying step and the residual heat dries off the water leaving, for example, calcium nitrate, calcium carbonate powder, and surfactant on the surface of the former. Other suitable coagulant solutions are also described in U.S. Patent No. 4,310,928 to Joung, which is incorporated herein in its entirety by reference thereto for all purposes.

The coated former is then dipped into a tank containing a natural rubber latex bath. The bath contains, for example, natural rubber latex, stabilizers, antioxidants, curing activators, organic accelerators, vulcanizers, and so forth. The stabilizers may, for example, be phosphate-type surfactants. The antioxidants may be phenol-based compounds, such as 2,2'-methylenebis (4-methyl-6-t-butylphenol). The curing activator may be zinc oxide. The organic accelerator

may be dithiocarbamate. The vulcanizer may be sulfur or a sulfur-containing compound. If these materials are used, the stabilizer, antioxidant, activator, accelerator and vulcanizer may be dispersed into water to avoid crumb formation by using a ball mill. This dispersion is then mixed into the latex. The former is dipped into one or more latex baths a sufficient number of times to build up the desired thickness on the former. By way of example, the substrate body 24 may have a thickness of from about 0.1 to about 0.3 millimeters.

A bead roll station may, in some embodiments, be utilized to impart a cuff to the glove 20. For instance, the bead roll station may contain one or more bead rolls such that the former is indexed therethrough to be provided with cuffs. The latex-coated former is then dipped into a leaching tank in which hot water is circulated to remove the water-soluble components, such as residual calcium nitrates and proteins contained in the natural latex. This leaching process may continue for about twelve minutes with the tank water being about 49°C.

The latex-coated former may then be dipped into a solution to form the hydrogel coating 26 of the glove 20. In one embodiment, the latex-coated former is dipped into an aqueous solution of a water-soluble hydrogel-forming polymer or a mixture of such polymers. The aqueous composition may, for instance, include from about 0.1 wt.% to about 30 wt.% of hydrogel-forming polymer(s), in some embodiments from about 0.5 wt.% to about 10 wt.% of hydrogel-forming polymer(s), and in some embodiments, from about 1 wt.% to about 5 wt.% of hydrogel-forming polymer(s). The amount of active agent employed may vary depending on the type of active agent, the type of hydrogel, etc. Specifically, hydrogels that provide a slow release rate may require a higher active agent content than hydrogels that provide a fast release rate. In most embodiments, for example, the aqueous solution may contain from about 0.0001 wt.% to about 30 wt.% of active agent(s), in some embodiments from about 0.001 wt.% to about 10 wt.% active agent(s), and in some embodiments, from about 0.1 wt.% to about 5 wt.% active agent(s). The aqueous solution may also contain other components. For example, in some embodiments, the aqueous solution may contain from about 0.01 wt.% to about 10 wt.% crosslinking agent(s), in some embodiments from about 0.1 wt.% to about 5 wt.% crosslinking agent(s), and in some embodiments, from about 0.2 wt.% to about 2 wt.% crosslinking agent(s). Water typically

constitutes from about 70 wt.% to about 99.9 wt.%, and in some embodiments, from about 90 wt.% to about 99 wt.% of the aqueous solution. Additional dips may be utilized to build up the desired thickness of the coating 26. Further, the coating 26 may alternatively be applied to the former before it is dipped into the latex-containing bath(s).

It should also be understood that other components may be present in the coating mixture. For example, to initiate or speed up the crosslinking process, a catalyst, such as p-toluene sulfonic acid or hydrochloric acid, may be utilized. In addition, polymerization initiators may also be utilized, such as described in U.S. Patent No. 6,242,042 to Goldstein, et al., which is incorporated herein in its entirety by reference thereto for all purposes. A pH adjuster, such as an acid or base, may be also be added to achieve a certain pH.

Once coated, the former is sent to a curing station (e.g., oven) where the natural rubber is vulcanized and the hydrogel-forming polymer is crosslinked. If desired, the curing station may initially evaporate any remaining water and then proceed to the higher temperature vulcanization and crosslinking steps. For instance, curing of the hydrogel-forming polymer may be initiated by heating at a temperature from about 25°C to about 200°C, in some embodiments from about 50°C to about 150°C, and in some embodiments from about 70°C to about 120°C, for a period of time of from about 1 minute to about 12 hours, in some embodiments from about 5 minutes to about 5 hours, and in some embodiments, from about 10 minutes to about 1 hour. Vulcanization may occur at the same time as the crosslinking of the hydrogel-forming polymer, or at a different time. If desired, the oven may be divided into four different zones with a former being conveyed through the zones of increasing temperature. One example is an oven having four zones with the first two zones being dedicated to drying, and the second two zones being primarily to vulcanization and crosslinking of the hydrogel polymer. Each of the zones may have a slightly higher temperature, for example, the first zone at about 80°C, the second zone at about 95°C, a third zone at about 105°C, and a final zone at about 115°C. The residence time of the former within a zone may, for instance, be about 10 minutes.

The former may then be transferred to a stripping station. The stripping station may involve automatic or manual removal of the glove 20 from the former.

For example, in one embodiment, the glove 20 is manually removed from the former by turning it inside out as it is stripped from the former. After being removed from the former, the glove 20 may be rinsed in water and dried.

Optionally, a coating may be applied to enhance the gripping properties of the glove 20. For example, in one embodiment, a silicone emulsion (e.g., DC 365, available from Dow Corning) is first thoroughly mixed with water using a high shear mixer to achieve a homogeneous solution having the desired solids content. Thereafter, the resulting emulsion may then be applied to the surface 30 of the substrate body 24 in a variety of different ways. For instance, in one embodiment, the glove 20 is immersed in a tumbler for a certain period of time (e.g., 1-10 minutes) during which the grip surface 30 is rinsed with the silicone emulsion. Alternatively, the grip surface 30 may be sprayed with the silicone emulsion using a conventional spray nozzle. Once applied with the silicone emulsion, the glove 20 is then dried. For example, in some embodiments, the glove 20 may be dried at a temperature of from about 20°C to about 200°C, and in some embodiments, from about 35°C to about 115°C.

After the drying process, the glove is optionally inverted and halogenated. Halogenation (e.g., chlorination) may be performed in any suitable manner known to those skilled in the art. Such methods include (1) direct injection of chlorine gas into a water mixture, (2) mixing high-density bleaching powder and aluminum chloride in water, (3) brine electrolysis to produce chlorinated water, and (4) acidified bleach. Examples of such methods are described in U.S. Patent Nos. 3,411,982 to Kavalir; 3,740,262 to Agostinelli; 3,992,221 to Homsy, et al.; 4,597,108 to Momose; and 4,851,266 to Momose, 5,792,531 to Littleton, et al., which are incorporated herein in their entirety by reference thereto for all purposes. In one embodiment, for example, chlorine gas is injected into a water stream and then fed into a chlorinator (a closed vessel) containing the glove. The concentration of chlorine may be monitored and controlled to control the degree of chlorination. The chlorine concentration is typically at least about 100 parts per million (ppm), in some embodiments from about 200 ppm to about 3500 ppm, and in some embodiments, from about 300 ppm to about 600 ppm, e.g., about 400 ppm. The time duration of the chlorination step may also be controlled to control the degree of chlorination and may range, for example, from about 1 to about 10

minutes, e.g., 4 minutes. Still within the chlorinator, the glove 20 may then be rinsed with tap water at about room temperature. This rinse cycle may be repeated as necessary. Once all water is removed, the glove 20 is tumbled to drain excess water.

Although various constructions and techniques for forming elastomeric articles have been described above, it should be understood that the present invention is not limited to any particular construction or technique for forming the article. For example, the layers described above may not be utilized in all instances. Additionally, other layers not specifically referred to above may be utilized in the present invention. For example, in one embodiment, an additional lubricant may be applied over the hydrogel coating 26 so long as it does not adversely affect the ability of the active agent be controllably released. Although not required, the lubricant may cover those portions of the surface 28 not covered by the coating 26. Suitable lubricants include silicone emulsions, such as described in U.S. Patent Application Publication No. 2003/0118837 to Modha, et al., which is incorporated herein in its entirety by reference thereto for all purposes.

The present invention may be better understood with reference to the following example.

EXAMPLE

The ability to form an elastomeric glove in accordance with the present invention was demonstrated. Initially, a pre-heated, glove-shaped former was dipped into a coagulant solution that contained calcium nitrate, calcium carbonate, a surfactant, and water. The coated former was then dipped into a dip tank containing compounded, pre-vulcanized natural rubber latex. After dipping, the former was removed from the natural rubber latex dip tank and leached with water. Thereafter, the latex-coated former was cured in an oven at a temperature of 115°C for about 20 minutes. The glove was manually removed from the former by turning the glove inside out as it was stripped from its corresponding former. After being removed from the former, the glove was also rinsed in deionized water. The thickness of the resulting glove was 0.24 millimeters. After the drying process, the glove was turned inside out and placed into a chlorinator. Chlorine gas mixed with a water stream was injected into the chlorinator to chlorinate the donning surface of the glove. The chlorine concentration was 875 ppm and the pH was 1.8. The

glove was immersed in the chlorine solution for 4 minutes. After chlorination, the glove was inverted and dried at a temperature of about 55°C for 40 minutes.

The latex glove was then dipped into a solution containing 96.725 wt.% water, 0.25 wt.% melamine-formaldehyde (crosslinking agent), 0.025 wt% of p-toluene sulfonic acid (a catalyst), and 3 wt.% of a hydrogel-forming polymer formed from hydroxy ethyl acrylate and acrylic acid monomers, which was obtained from Ortec, Inc. of Easley, South Carolina. The mixture was then heated to a temperature of about 120°C for about 18 minutes to crosslink the polymer and form a hydrogel coating on the glove.

To test the ability of the hydrogel-coated glove to controllably release an active agent, it was immersed for 7 hours in an aqueous solution containing 99.5 wt.% water and 0.5 wt.% of a dye (Fiber Identification Stain #7, available from Dupont). A comparative glove was also immersed for 7 hours in the same aqueous solution. The comparative glove was identical to the test glove, except that it did not contain a hydrogel coating. Each glove was removed from the dye solution and rinsed several times with water to remove excess dye. The gloves were then dried overnight in an oven at 60°C. Thereafter, 50 milliliters of water was injected into the hand-receiving cavity formed by each glove and allowed to remain for 2 minutes. The water was poured out, and an additional 50 milliliters of water was injected into the glove and allowed to remain for 3 minutes. This process was repeated with water being injected into the glove and allowed to remain for varying periods of time up to 280 minutes of contact time. The absorbance values of the water samples were then measured at a wavelength of 547 nanometers with a UV-visible spectrophotometer, which is commercially available from Shimadzu of Kyoto, Japan (Model No. UV-1601). The absorbance correlated with the amount of dye that had diffused out of the glove and into the water.

The results are shown in Fig. 3. As indicated, an increased amount of the dye was detected for diffusion times ranging up to about 275 minutes. This exemplifies the ability of an active agent to be controllably released from a hydrogel coating present on a glove in accordance with the present invention. On the other hand, the glove that did not contain the hydrogel coating showed no ability to pick up the dye.

While the invention has been described in detail with respect to the specific embodiments thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these embodiments. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.